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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,491	07/29/2003	Michael R.S. Hill	9095DIV (2620/29)	7444

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Jeffrey J. Hohenshell
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EXAMINER

MULLEN, KRISTEN DROESCH

ART UNIT PAPER NUMBER

3766

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/629,491

Applicant(s)

HILL ET AL.

Examiner

Kristen Mullen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/10/06.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Information Disclosure Statement

2. Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. See MPEP 609.05(b). Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

3. The information disclosure statement filed 10/10/06 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Missing copies of references are:

Norbrega et al.
Hageman et al.

4. The information disclosure statement filed 10/10/06 fails to comply with 37 CFR 1.98(a)(3) because it does not include a copy of a translation or a concise explanation of the

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relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered. References not conforming with 37 CFR 1.98(a)(3) are:

DE 2811325

JP 2001505980

JP200507363

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-3, and 9-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (6,304,777) in view of Medtronic (WO 97/40885). Ben-Haim shows a system comprising an electrical sensor comprising cardiac stimulation electrodes, an indicator, a stimulator in communication with the sensor, the stimulator comprises at least one cardiac stimulation electrode that is the same as the sensor electrodes; and a cardiac stimulator in communication with the sensor (Col. 5, line 61-Col. 6, line 3; Col. 8, lines 5-23; Fig. 1). Although Ben-Haim shows a stimulator that inhibits beating of the heart, Ben-Haim teaches it is well known to stimulate the vagus nerve with an electrode that inhibits beating of the heart (Col. 1, lines 38-50). Medtronic shows a vagal nerve stimulator that inhibits beating of the heart. It would have been obvious to one with ordinary skill in the art at the time the invention was made to employ the vagal nerve stimulator that Medtronic teaches for the stimulator of Ben-Haim,

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wherein so doing would amount to a mere substitution of one functional equivalent for another that would work equally well on the Ben-Haim device.

7. Claims 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (6,304,777) in view of Medtronic (WO 97/40885) as applied to claim 1 above. Ben-Haim and Medtronic are as explained before. Although Ben-Haim does not show a breathing regulator comprising a respirator or at least one nerve stimulation electrode, attention is directed to Medtronic which teaches a similar device and uses electrodes to stimulate the phrenic nerve and a respirator in order to still the lungs during the medical procedure while the beating of the heart is inhibited (Page 9, lines 14-22). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to stop breathing using phrenic nerve stimulation and a respirator when the state of the cardiac tissue is a non-contracting state as Medtronic teaches in order to still the lungs during the medical procedure.

8. Claims 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (6,304,777) in view of Medtronic (WO 97/40885) as applied to claim 1 above. Ben-Haim and Medtronic are as explained before. Although Ben-Haim and Medtronic fail to specifically teach a drug delivery means, it is well known to utilize a drug delivery means such as a needle and syringe or a catheter during medical procedures in order to deliver anesthetics. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the system of Ben-Haim and Medtronic to include a drug delivery means such as a needle and syringe or a catheter since it is well known well known to utilize such drug delivery means to deliver anesthetics during medical procedures.

The functional language and statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art. The examiner considers the following language to be exemplary statements of intended use:

“to sense . . .”
“to indicate . . .”
“to inhibit . . .”
“to stimulate . . .”
“to ensure . . .”

Response to Arguments

9. Applicant's arguments filed 9/26/06 have been fully considered but they are not persuasive. Applicant argues that Ben-Haim and Medtronic do not determine when an escape beat is imminent and does not inhibit beating of the heart when an escape beat is imminent. However, this recitation in claim 1 is a statement of intended use that does not result in a structural difference distinguishable over the prior art. Applicant also argues that Ben-Haim and Medtronic do not show that the nerve stimulator is off when the cardiac stimulator is on and vice versa. As explained before, this is considered a statement of intended use which does not distinguish over the prior art. If the nerve stimulator and cardiac stimulator were programmed to perform these functions it would result in a structural difference since the act of programming results in a physical difference (albeit a difference in the physical arrangement of bytes).

Conclusion

10. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114.

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See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Kristen D. Mullen
Patent Examiner-Temp. Full Signatory
Authority
Art Unit 3766

kdm